6. (**Amended**) A fragment of SEQ ID NO: 2 ~~DETH~~ that induces apoptosis.

REMARKS

Claims 1-9 are the pending claims in the present application, and claims 1-6 are currently under consideration. Applicants will cancel non-elected claims upon indication of allowable subject matter. Applicants add new claims 10-13. Support for the subject matter of these claims is found throughout the application. No new matter has been entered. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note with appreciation that the response filed February 25, 2002 has been entered.

2. Applicants' amendments to the specification are believed to obviate the objections.

3. Applicants thank the Examiner for considering the Information Disclosure Statement. Applicants note that reference JR has been considered.

4. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

Claims 1-4 and 6 are specifically rejected because the recitation of "DETH" with reference to a particular sequence is allegedly indefinite. Applicants contend that the term DETH is defined in the specification, and accordingly one of skill in the art can readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, to expedite prosecution, Applicants have amended the claims to make reference to an amino acid sequence disclosed in the present application. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of the rejection are respectfully requested.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to convey to one skilled in the art that applicants had possession of the claimed invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

The standard for assessing compliance with the written description requirement has been outlined in detail by the Guidelines for the Examination of Patent Applications which indicate that possession of the invention can be demonstrated in many ways including "by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention."

The Examiner has cited The Regents of the University of California v. Eli Lilly and Co. to support the basis for this rejection, however Applicants content that the findings of the Federal Circuit in this case actually support Applicants' position (The Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1997 U.S. App. LEXIS 18221, 43 U.S.P.Q.2D (BNA) 1398 (Fed. Cir. 1997)). In this case, the Federal Circuit addressed the question of how to adequately describe a genus of materials. In outlining that which constitutes an adequate description of a genus with respect to genetic material, the court asserted that adequate description requires more than the gene or protein name.

> "[A] cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA. See Fiers, 984 F.2d at 1171, 25 U.S.P.Q.2D (BNA) at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus **or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."** (emphasis supplied) 119 F.3d at 1566

Accordingly, for the description of a genetic invention to be deemed adequate to describe the genus that the claims encompass requires either a recitation of the structure (i.e., sequence) of a representative number of members of the genus **or** a recitation of the common features of the members of the claimed genus. This "recitation of structural features common to the members of the genus" is analogous to the way in which chemical genera are described, and provides features

which readily allow one of skill in the art to recognize the claimed invention. This is in contrast to the way in which the claimed subject matter was recited in Lilly, where nucleic acids were claimed by the name of the cDNA and its origin, without any recitation of sequence or common structural or functional characteristics that could be used by one of skill in the art to readily envision the claimed sequences.

> "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." 119 F.3d at 1566

Applicants submit that the pending claims define the claimed subject matter in terms of generic formulae that indicate with specificity what the generic claims encompass, and accordingly meet the guidelines set forth above and comply with the written description requirement. Applicants have disclosed nucleic acid and amino acid sequences corresponding to a DETH protein. Furthermore, Applicants have provided not only the sequence of this protein, but also detailed information concerning the structure of the protein including relevant functional domains of the protein (page 5, lines 6-11).

In addition to the extensive sequence and structural data, Applicants describe a functional activity that is a key distinguishing feature of a DETH protein (Example 3). The ability of a DETH protein to induce apoptosis is a feature that defines the polypeptides of the invention, and is used throughout the claims to help clearly point out characteristics of the claimed polypeptides, as well as claimed variant polypeptides. In short, the specification details the identification of DETH nucleic acid and amino acid sequences, and describes the corresponding proteins both structurally and functionally based on their ability to induce apoptosis. Applicants'

description based on both structural and functional criteria stands in sharp contrast to the way in which sequences were described in *Lilly*. Accordingly, Applicants submit that based on both the Guidelines for the Examination of Patent Applications, and based on the recent holdings of the Federal Circuit, Applicants have satisfied the requirements under 35 U.S.C. 112, first paragraph.

Given Applicants' disclosure of the structural and functional features that describe the claimed proteins, Applicants submit that one of skill in the art can readily envision the claimed subject matter. Accordingly Applicants contend that the pending claims satisfy all of the requirements under 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of this rejection is respectfully requested.

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Deen et al. (United States Patent No. 6013476). Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

In accordance with MPEP 2131 and with the Courts, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros.v. Union Oil Co, of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Deen et al. fail to satisfy the criteria clearly delineated by the MPEP and the courts for anticipating the claimed invention. As pointed out by the Examiner, Deen et al. does not teach or suggest that the disclosed protein induces apoptosis. Furthermore, Deen et al. does not identify the discrete functional domains of the protein, such as the death domain which Applicants identified as comprising amino acid residues 168-240 of SEQ ID NO: 2 (page 5, line 11). Accordingly, the compositions disclosed by Deen et al. do not anticipate Applicants' invention.

The Examiner has argued that although Deen et al. fail to explicitly teach each and every limitation of the pending claims, the compositions disclosed by Deen et al. are inherently the same as the presently claimed compositions. However, Applicants point out that the MPEP and the Courts have established a very high threshold for rejecting claims based on characteristics which are allegedly inherently present in a prior art reference. "[T]he fact that a certain result or

characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."

> "In re Rijckaert, 9 F.3d 1531, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. **Inherency, however, may not be established by probabilities or possibilities** (emphasis added). The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-1951 (Fed Cir. 1999) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fasterning element, either expressly or inherently.)" **MPEP 2112**

Applicants have disclosed proteins characterized by a particular functional feature: the ability to induce apoptosis. Deen et al. provide no evidence to demonstrate or suggest that the compositions disclosed in U.S. Patent No. 6013476 possess this activity. Absent such specific evidence and absent specific guidance to suggest that the cells **would** possess these characteristics, Deen et al. fail to satisfy the criteria for anticipating the presently claimed cells.

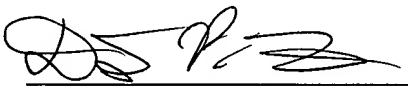
Additionally, Applicants point out that Deen et al. is completely silent on the identity of particular functional domains of these proteins. Accordingly, Applicants' identification of particular apoptosis inducing domains of the disclosed full length amino acid sequence, as recited in claims 6, 11, 12 and 13, is in no way anticipated by Deen et al.

Applicants contend that the compositions of the present invention are not anticipated by the teachings of Deen et al. The compositions of Deen et al. fail to meet each and every limitation set forth in the claims. Furthermore, Deen et al. fail to provide any guidance to even suggest that the disclosed compositions inherently possess the characteristics of the presently claimed compositions, and Deen et al. provides no guidance as to the regions of the full length protein which correspond to particular functional or structural domains. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,



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